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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/975,490 | 10/11/2001 | Koh Kimura | 14991 | 9704 |

7590 01/26/2004
Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530-0299

EXAMINER

PANTUCK, BRADFORD C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3731

18

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,490

Applicant(s)

KIMURA ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 7, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 and 28-31 is/are allowed.
- 6) ☒ Claim(s) 17-27 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).
Correction of the following is required: the term “clip operating device” in line 8 of claim 17 lacks antecedent basis in the specification. It is suggested that Applicant replace this phrase with the term “clip manipulating device”, which does have antecedent basis in the specification. Similarly, the term “an operating wire” in line 8 of claim 17 lacks antecedent basis in the specification. It is suggested that Applicant replace this phrase with the term “a manipulating wire”, which does have antecedent basis in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17-27, 32, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding Claim 17, it is unclear what Applicant is referring to, when Applicant refers to an “operating wire” and a “clip operating device.” Applicant should use language consistent with the specification, as mentioned above.
3. Regarding Claim 32, In line 3, the phrase “and is engaged to each other” is unclear. It is suggested that Applicant adjusts the language to read “holding means is

a stepped section that is provided at each of the arms of said clip, for engaging said arms to each other.”

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,402,765 to Monassevitch et al. Monassevitch discloses a physiological tissue clip (170) capable of being arbitrarily opened and closed, which is made out of a super-elastic alloy. In fact, Monassevitch teaches making the entire device out a super-elastic material [Column 7, lines 25-28]. Monassevitch discloses a tightening ring (142/144) mounted on both components of the clip (172/174). The tightening ring (142/144) closes the clip [Column 8, lines 15-22]. A link member (180) is inserted into the bottom tightening ring (144) when the clip (172/174 closes)—i.e. it advances into and through the interior of ring (144). *Monassevitch's clip is made in a V-shape, as viewed from the perspective shown in Figure 3B.*

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,189 to Matsuno in view of U.S. Patent No. 6,402,765 to

Monassevitch et al. Regarding Claims 34 and 40, Matsuno discloses the invention as claimed (as described above) except that his clip is not a super-elastic alloy.

However, Monassevitch teaches that one would make a surgical clip for clipping tissue out of shape memory material in order to enable portions of tissue to be pressed together when body temperature is reached (but not before then). He also teaches that surgical clips made out of super-elastic materials are easy to design and are inexpensive to manufacture [Column 1, lines 38-47]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Matsuno's clip out of a super elastic alloy in order to allow the target tissues to be clamped *upon the reaching of the body temperature*.

6. Regarding Claim 35, Matsuno's modified clip is bent at its center portion. Additionally, the modified clip has an opening width capable of ligating physiological tissue [see Fig. 5]. In fact, the purpose of the device is to clip tissue [Column 1, lines 5-8].
7. Regarding Claim 37, Matsuno's clip can be elastically deformed/restored from a closed state capable of being housed in a forceps channel [see Fig. 5] of an endoscope to an opened state [see Fig. 6] capable of ligating tissue.
8. Regarding Claim 39, the Matsuno's clip, as modified by Monassevitch, is composed of a planar super-elastic alloy. Figure 4 shows the clip (2), which has particularly planar end portions.

Allowable Subject Matter

9. Claims 17-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
10. Claims 1-16 and 28-31 are allowed.
11. The following is an examiner's statement of reasons for allowance:

U.S. Patent No. 5,766,189 to Matsuno does not read on claim 28. When Matsuno's clip is pulled, his holding means (inner surface of component 7) does not exert "a holding force that permits release of the clip from the opened state when the clip is pulled," as set forth by the applicant. Matsuno's clip is released from its opened state (as shown in Figure 6) only by *pushing it* distally.

Response to Arguments

12. Applicant's arguments, see last paragraph on page 16 and first three paragraphs on page 17, filed November 7th, 2003, with respect to Claim 17 have been fully considered and are persuasive. The rejection of Claim 17 under **35 USC § 102** has been withdrawn.
13. Applicant's arguments filed November 7th, 2003 with regards to Claim 34 have been fully considered but they are not persuasive. Monassevitch's clip is made in a V-shape, as viewed from the perspective shown in Figure 3B. Matsuno's clip has a V-shape, just like the Applicant's clip. It is obvious to make Matsuno's clip out of a super-elastic alloy, as taught by Monassevitch et al. *It is suggested that Applicant cancel claims 34-39.*

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 3,958,576 to Komiya

U.S. Patent No. 4,367,746 to Derechinsky

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP

January 15, 2004

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700